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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

firre application of

Docket No: Q77569

TANABE, Tadashi, et al.

Appln. No.: 10/663,749

Group Art Unit: 1644

Confirmation No.: 5604

Examiner: Kim, Y.

Filed: September 17, 2003

For:

ANTIBODIES SPECIFIC TO HUMAN PROSTACYCLIN SYNTHASE

REQUEST FOR CORRECTED OFFICIAL FILING RECEIPT

ATTN: Office of Initial Patent Examination

Filing Receipt Correction

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

We enclose a copy of the Official Filing Receipt for the above-identified application and request the following correction(s):

Please correct the "Domestic Priority data as claimed by applicant" to read as follows:

This application is a CIP of 10/608,536 06/30/2003 PEND which is a CON of 09/670,582 09/27/2000 ABN which is a CON of 09/037,758 03/10/1998 ABN which is a DIV of 08/578,709 12/28/1995 PAT 5,814,509

Applicants made the proper benefit claim in the application by including reference to the prior applications in the first paragraph of the specification, as permitted under 37 C.F.R. §1.78(a)(2).

However, as the direct parent application (10/608,536) was filed less than three months prior to the instant application, the serial number of the parent application was unavailable.

However, applicants referred to the parent application by attorney docket number (Q76409) and filing date (June 30, 2003). As shown on the enclosed Official Filing Receipt for the parent application, the same docket number corresponds to U.S. application number 10/608,536.

Applicants also note that the first paragraph of the specification contained an error in reference to the filing date of U.S. application number 09/037,758. While the first paragraph of the specification listed the filing date of this application as January 10, 1998, it was in fact filed March 10, 1998.

Moreover, the first paragraph of the specification contained an error in the serial number of the first application in the series (08/578,709). While the first paragraph of the specification listed the serial number as 08/578,706, it was in fact 08/578,709.

An amendment was filed in the instant application November 21, 2005, to correct these errors. A copy of the amendment is enclosed herewith, along with the date-stamped filing receipt.

Finally, Applicants note that the Declaration and Power of Attorney filed in the instant application on December 19, 2003, included the same errors. Accordingly, Applicants submitted herewith a Substitute Declaration and Power of Attorney, executed by Applicants, showing the correct serial numbers and filing dates for each of the prior applications.

In view of the above, Applicants respectfully request issuance of an updated and corrected Official Filing Receipt.

REQUEST FOR CORRECTED OFFICIAL FILING RECEIPT U.S. Appln. No. 10/663,749

Q77569

As a benefit claim (albeit, with errors) was made in the instant application within the time period set forth in 37 C.F.R. §1.78(a)(2), no petition is believed to be required under 37 C.F.R. §1.78(a)(3).

Respectfully submitted,

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON OFFICE 23373
CUSTOMER NUMBER

Drew Hissong

Registration No. 44,765

Date: November 30, 2005



United States Patent and Trademark Office

NOV 3 0 2005

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/663,749	09/17/2003 -	1645	880	Q77569	14	20 ~	3 -

23373 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 CONFIRMATION NO. 5604
UPDATED FILING RECEIPT
OC000000011821825

Date Mailed: 02/03/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Tadashi Tanabe, Toyonaka-shi, JAPAN; Ababashi Tanabe, Toyonaka-shi, Toyonaka-shi,

Domestic Priority data as claimed by applicant

Foreign Applications

JAPAN 114316/1994 04/28/1994 V

If Required, Foreign Filing License Granted: 11/26/2003

Projected Publication Date: 05/13/2004

Non-Publication Request: No

Early Publication Request: No.

Title

Antibodies specific to human prostacyclin synthase

Preliminary Class

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).





United States Patent and Trademark Office

NOV 3 0 2005

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/608,536	06/30/2003	1645	750	Q76409	13	12	2

23373 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 CONFIRMATION NO. 8239
CORRECTED FILING RECEIPT
OC000000016480737

Date Mailed: 07/08/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Tadashi Tanabe, Osaka, JAPAN;

Power of Attorney:

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Peter Olexy-24513 J OSHA-24625

Louis Gubinsky-24835

Neil Siegel-25200 Alan Kasper-25426

Domestic Priority data as claimed by applicant

This application is a CON of 09/670,582 09/27/2000 ABN which is a CON of 09/037,758 03/10/1998 ABN which is a DIV of 08/578,709 12/28/1995 PAT 5,814,509

Foreign Applications

JAPAN 114316/1994 04/28/1994

If Required, Foreign Filing License Granted: 10/20/2003

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/608,536

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

Antibodies specific to human prostacyclin synthase

Preliminary Class

530

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



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In re application of

TANABE, Tadashi, et al.

Appln. No.: 10/663,749

Confirmation No.: 5604

Filed: September 17, 2003

For: ANTIBODIES SPECIFIC TO HUMAN PROSTACYCLIN SYNTHASE

PAPER(S) FILED ENTITLED:

1. AMENDMENT UNDER 37 C.F.R. §1.111

2. INFORMATION DISCLOSURE STATEMENT UNDER

37 C.F.R. §§ 1.97 and 1.98

3. PTO/SB/08 A & B (modified)

SUGHRUE MION, PLLC

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

DOCKET NO.: Q77569

ATTORNEY/SEC: GK/DXH

Group Art Unit: 1644

Examiner: Kim, Y.

Date Filed: November 21, 2005





PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q77569

TANABE, Tadashi et al.

Appln. No.: 10/663,749

Group Art Unit: 1644

Confirmation No.: 5604

Examiner: Kim, Y.

Filed: September 17, 2003

For:

ANTIBODIES SPECIFIC TO HUMAN PROSTACYCLIN SYNTHASE

AMENDMENT UNDER 37 C.F.R. § 1.111

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated August 24, 2005, please amend the aboveidentified application as follows on the accompanying pages.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph no. [01] with the following amended paragraph:

This application is a continuation-in-part application of USSN 10/608,536 (attorney docket Q76409)-filed June 30, 2003, in turn a continuation of USSN 09/670,582 filed September 27, 2000 (now abandoned), in turn a continuation of USSN 09/037,758, filed March January-10, 1998 (now abandoned), in turn a divisional of USSN 08/578,709 08/578,706-filed December 28, 1995 (now U.S. Patent 5,814,509).

Please delete pages 42-51 (Sequence Listing) of the application.

Please renumber pages 52-54 (claims) as pages 42-44.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

- 1.-12. (canceled).
- 13. (currently amended) An isolated or purified antibody that specifically binds an epitope consisting of residues 1-12 of SEQ ID NO:18 specific to human prostacyclin synthase produced by using, as an immunogen, a polypeptide comprising an isolated or purified whole or part having immunological activity of an amino acid sequence of a human proctacyclin synthase substantially depicted in SEQ ID NO: 18.
- 14. (currently amended) The antibody according to claim 13, wherein said antibody which is a monoclonal antibody.
- 15. (currently amended) The antibody according to claim 14, wherein said antibody which is a purified IgG fraction.
- 16. (currently amended) The antibody according to claim 13, wherein said antibody which is a polyclonal antibody.
- 17. (currently amended) TheAn antibody according to claim 13, wherein said antibody specifically binds to a the polypeptide comprising said epitope comprises an amino acid sequence as depicted in SEQ ID NO: 18.
- 18. (currently amended) The antibody according to claim 17, wherein said antibody which is a monoclonal antibody.

- 19. (currently amended) The antibody according to claim 18, wherein said antibody which is a purified IgG fraction.
- 20. (currently amended) The antibody according to claim 17, wherein said antibody which is a polyclonal antibody.
- 21. (new) The antibody according to claim 13, wherein said antibody binds to human prostacyclin synthase and does not bind to bovine prostacyclin synthase.
- 22. (new) An isolated or purified antibody that specifically binds an epitope consisting of residues 1-12 of SEQ ID NO:18, said antibody produced using an immunogen comprising a polypeptide, wherein said polypeptide comprises residues 1-12 of SEQ ID NO:18.
- 23. (new) The antibody of claim 22, wherein said polypeptide consists of residues 1-12 of SEQ ID NO:18.
- 24. (new) The antibody of claim 22, wherein said immunogen further comprises complete Freund's adjuvant or keyhole limpet hemocyanin.
- 25. (new) A method for producing an antibody that specifically binds an epitope consisting of residues 1-12 of SEQ ID NO:18, comprising;
- (a) administering an immunogen comprising a polypeptide to an animal, wherein said polypeptide comprises residues 1-12 of SEQ ID NO:18, and
- (b) isolating an antibody from said animal of (a) that specifically binds an epitope consisting of residues 1-12 of SEQ ID NO:18.
- 26. (new) The method according to claim 25, wherein said polypeptide consists of residues 1-12 of SEQ ID NO:18.

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. Appln. No. 10/663,749

Q77569

- 27. (new) The method according to claim 25, wherein said immunogen further comprises complete Freund's adjuvant or keyhole limpet hemocyanin.
- 28. (new) The method according to claim 25, wherein said antibody has the following properties (A) and (B):
 - (A) specifically binds human prostacyclin synthase, and
 - (B) does not bind bovine prostacyclin synthase.
- 29. (new) The method according to claim 25, wherein said antibody specifically binds human prostacyclin synthase alone.

REMARKS

Claims 1-20 are all the claims pending in the application; claims 1-12 have been withdrawn from consideration; claims 13-20 have been rejected.

Upon entry of this amendment, claims 1-12 will be canceled, new claims 21-29 will be added, and claims 13-29 will be pending.

New claims 21-29 are fully supported by the specification. Support for claim 21 may be found at paragraph [0176]. Support for claims 22-29 may be found, for example, in Example 7, beginning at page 37 of the specification.

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Information Disclosure Statement

With the Office Action dated August 24, 2005, the Examiner returned copies of the document lists submitted with the Information Disclosure Statements (IDS) in this application on December 19, 2003, and April 4, 2005.

As to the document list submitted April 4, 2005, the Examiner crossed through the Gryglewski et al. and Pereira et al. citations, acknowledging only the Weksler et al. citation. As to the document list submitted December 19, 2003, the Examiner only acknowledged consideration of the Ngo et al. document.

At paragraph 3 of the Office Action, the Examiner states that none of the other references were provided.

Applicants respectfully note that each of the documents cited on the document lists was either provided to the Examiner in one of the parent applications, or cited by the Examiner on a Form PTO 892 during prosecution of one of the parent applications. As set forth in 37

C.F.R. §1.98(d), copies of documents provided in an earlier application do not need to be provided if the earlier application is cited in the IDS. Because the IDS filed in the pending application cited parent application number 10/608,536, which claims benefit of other applications in which the documents were first submitted, the Examiner is respectfully requested to obtain copies of the documents from the parent applications.

Submitted herewith is a supplemental IDS, listing each of the documents that has not yet been acknowledged by the Examiner, as well as one additional document (Hara et al.) cited in parent application number 09/037,758 but mistakenly omitted from the document lists filed with the IDS in the pending application.

Applicants respectfully request return of an initialed and signed copy of the document list, indicating the Examiner's consideration of each listed document.

II. Priority

In paragraph 4 of the Office Action, the Examiner states that Applicants' claim for domestic priority under 35 U.S.C. §119(e) is acknowledged. Applicants respectfully note that a claim for domestic priority under 35 U.S.C. §119(e) (i.e., to a prior filed U.S. provisional application) has not been made in the instant application.

III. Specification

At paragraph 5 of the Office Action, the Examiner notes that the first paragraph of the specification should be updated and corrected with regard to the priority application information.

Included herewith is an amendment to the specification in the manner suggested by the Examiner.

IV. Claim Rejections Under 35 U.S.C. §112

A. At paragraph 7 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner states claims 13 and 17 are indefinite for the following reasons: (i) the phrase "immunological activity" in claim 13 is ambiguous and unclear, and the metes and bounds of the claimed "immunological activity" is not defined; (ii) the term "part" in claim 13 is not defined; (iii) the phrase "substantially depicted" in claim 13, and the term "depicted" in claim 17, are ambiguous and unclear, and the metes and bounds of the claim limitation is not defined; and (iv) the phrase "part...of an amino acid sequence" recited in claim 13 is ambiguous as it may mean "a part of SEQ ID NO:2 as small as two amino acid residues."

Include herewith is amendment to the claims such that each of the terms and phrases objected to by the Examiner has been canceled from the claims.

In view of the amendment to the claims, the claims are definite as written. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 9 of the Office Action, claims 13-20 are rejected under35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that while the specification is enabling for an antibody that specifically binds to a peptide consisting of SEQ ID NO:18, it does not reasonably provide enablement for any antibody that binds "part" of SEQ ID NO:18 as recited in claim 13, or any antibody that binds a peptide as "substantially depicted" in SEQ ID NO:18.

Included herewith is an amendment to the claims such that the claims do not recite antibodies that bind to a "part" of SEQ ID NO:18 or antibodies that bind to a peptide as "substantially depicted" in SEQ ID NO:18.

In view of the amendment to the claims, the claims are fully enabled. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

C. At paragraph 10 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Examiner states that while Applicants are in possession of an antibody that specifically binds to the peptide of SEQ ID NO:18, they are not in possession of any antibody that binds to any polypeptide part, or any antibody that binds to any peptide as substantially depicted in SEQ ID NO:18.

As noted above, included herewith is an amendment to the claims such that the claims do not recite antibodies that bind to a "part" of SEQ ID NO:18 or antibodies that bind to a peptide as "substantially depicted" in SEQ ID NO:18.

In view of the amendment to the claims, the claims have adequate written description support in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Claim Rejections Under 35 U.S.C. §102

At paragraph 12 of the Office Action, claims 13-15 and 17-19 are rejected under 35 U.S.C. §102(b) as being anticipated by Weksler (1990).

The Examiner states that Weksler teaches a monoclonal antibody to PGI₂ synthase. The Examiner notes that in view of the limitation in claim 13 that the antigen is as "substantially

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. Appln. No. 10/663,749

depicted" in SEQ ID NO:18, the antibodies of the claim are not limited to those that bind SEQ ID NO:18, and the claim would encompass the antibodies of Weksler.

As discussed above, included herewith is an amendment to the claims such that the claims no longer recite an antibody that binds to a peptide as "substantially depicted" in SEQ ID NO:18. As Weksler does not teach an antibody that specifically binds to an epitope consisting of residues 1-12 of SEQ ID NO:18, Weksler does not teach each and every element of the pending claims. Therefore, Weksler does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

VI. Claim Rejections Under 35 U.S.C. §103

At paragraph 14 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Miyata et al. (1994) in view of Campbell (1984).

The Examiner states that Miyata et al. discloses the sequence information of human prostacyclin synthase, but does not teach antibodies raised against the protein. The Examiner cites to Campbell as teaching the advantages of antibodies, their use in diagnosis and treatment, and the customary practice of making antibodies even without a clear objective for their application. The Examiner concludes that one of ordinary skill in the art would have been motivated to make antibodies for the purpose of diagnosis and treatment, with a reasonable expectation of success.

In order for the Examiner to maintain a rejection under 35 U.S.C. §103, the Examiner must show (1) that the cited references teach each and every element of the claim, (2) that there is a suggestion or motivation in the cited references or the general knowledge of the art to

modify the references to make the claimed invention, and (3) that there is a reasonable expectation of success that the modification will yield the claimed subject matter. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP §2142.

Applicants respectfully assert that the Examiner has not established a *prima facie* showing of obviousness.

First, the cited art does not teach each and every element of the claimed invention. In particular, there is no teaching in either Miyata or Campbell of an antibody that specifically binds to the peptide of SEQ ID NO:18. That is, neither Miyata or Campbell teaches the particular species of peptide used by Applicants to produced antibodies (the 12 amino acid peptide of SEQ ID NO:18).

Second, there is no suggestion or motivation in either Miyata or Campbell to produce an antibody against the epitope formed by the peptide of SEQ ID NO:18. While Miyata may teach human prostacyclin synthase, no where in this publication is a suggestion or motivation to raise an antibody against the particular epitope of SEQ ID NO:18. *In re Deuel*, 51 F.3d 1552,1557, 34 USPQ2d 1210, 1214 ("[A] *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the claimed compounds* to a person of ordinary skill in the art." (emphasis in original)); *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.").

As stated in MPEP §2144.08(II)(A)(4), examiners must consider a number of factors when determining whether one of ordinary skill in the art would have been motivated to select the claimed species in view of a genus. These factors include the size of the genus. In this

regard, as the full-length polypeptide contains 500 amino acids, there are hundreds of different 12 amino acid peptides that could be derived from the full-length polypeptide. There is nothing in the cited art to suggest or motivate the skilled artisan to select the 12 amino acid peptide of SEQ ID NO:18 for use in the production of antibodies.

Examiners must also consider the express teachings of the art. Applicants note that the Examiner has not identified any teaching of using the peptide of SEQ ID NO:18 as the epitope against which antibodies may be raised. Neither is there any teaching of structurally similar peptides in the art that may be used in the production of antibodies that would motivate one of ordinary skill in the art to choose the peptide of SEQ ID NO:18.

Examiners also need to consider the predictability of the technology. While the skilled artisan may be able to produce antibodies to a given peptide, the binding specificity of the resulting antibody is not predictable for a particular antigen. As discussed in Example 7 (see paragraph 176) of the specification, the antibody raised against the 12 amino acid human peptide of SEQ ID NO:18 is highly specific as it binds human prostacyclin synthase, but does not bind bovine PGIS.

In view of these comments, Applicants respectfully contend that the neither Miyata nor Campbell, alone or in combination, teaches or suggests the claimed invention. Thus, as the Examiner has not established a *prima facie* case of obvious, Applicants request reconsideration and withdrawal of this rejection.

VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

AMENDMENT UNDER 37 C.F.R. § 1.111 U.S. Appln. No. 10/663,749

Q77569

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON OFFICE 23373
CUSTOMER NUMBER

Respectfully submitted,

Drew Hissong

Registration No. 44,765

Date: November 21, 2005

Docket No.: <u>Q77569</u>



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (37 C.F.R. 1.63)

特許出願宣言書および委任状(37 C.F.R. 1.63)

Japanese Lang	uage Declaration
私は以下の通り宣言します:	I hereby declare that:
各発明者の住所、郵送先、および国籍は下記氏名の後に 記載された通りです。	Each inventor's residence, mailing address, and citizenship are as stated below next to their name.
下記名称の発明に関し請求範囲に記載され特許出願がされている発明内容につき、下記に記載された発明者が本来かつ最初の発明者であると信じます。	I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
	ANTIBODIES SPECIFIC TO HUMAN PROSTACYCLIN
	SYNTHASE
□ 上記発明の明細書は本書に添付されます。	the specification of which is attached hereto
または	OR
□ 上記発明は米国出願番号あるいはPCT国際出願番号□ (確認番号) として (年_月_日に出願され、	was filed on <u>September 17, 2003</u> as United States Application Number or PCT International Application Number <u>10/663,749</u> (Confirmation No. <u>5604</u>),
する場合)。	and was amended on (if applicable)
私は補正が上に明示された場合は補正された特許請求範 囲を含む前記明細書の内容を検討し、理解していること をここに表明します。	I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.
私は一部継続出願の場合先行出願の出願日から一部継続 出願の国内あるいはPCT国際出願日までの期間中に入手 された重要な情報を含み、37 C.F.R. 1.56に定義される 特許性に肝要な情報について開示義務があることを認め ます。	I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including for continuation-in-part application(s), material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Japanese Language Declaration

April 28, 1994

(Filing Date) (出願日)

(Filing Date) (出願日)

abandoned

私は35 U.S.C. 119(a)-(d) あるいは (f), または365(b)に基づき特許、発明者、あるいは植物育種 家証書の下記外国出願、または365(a)に基づきアメリカ 合衆国以外の少なくとも1ヶ国を指定した下記PCT国際出 願についての外国優先権特典をここに主張するとともに 下記項目にx印を付けることにより優先権を主張する出 願以前の出願日を有する特許、発明者、あるいは植物育 種家証書の外国出願またはPCT国際出願を示します。

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application(s) which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application(s) having a filing date before that of the application on which priority is claimed.

> Priority Claimed? 優先権の主張 ?

> > No

無し

Yes

有り

 \boxtimes

Prior Foreign Application Nu 先行外国出願番号	mber(s)
114316/1994	JP
(Application Number)	(Country)
(出願番号)	(国名)
(Application Number)	(Country)
(出願番号)	(国名)
私は35 U.S.C. 119(e)に基づ 優先権をここに主張します	き下記の米国仮特許出願の国内 - 。
(Application Number)	(Filing Date)
(出願番号)	(出願日)
(Application Number)	(Filing Date)
(出願番号)	(出願日)
365(c)に基づき米国を指定 ここに主張し、本特許出廊 容が35 U.S.C. 112の最初な 行米国あるいはPCT国際特 において37 C.F.R. 1.56に 肝要で、先行特許出願の	き下記米国特許出願、あるいは する下記PCT国際出願の利益を 同内特許請求範囲の各項目の内 の項に規定される方法により先 許出願で開示されていない限り 定義される本出願の特許性に 出願日から本特許出願の国内 での期間中に入手された情報 ことを認めます。
Prior U.S. or International Ap 先行米国あるいは国際出願	番号
PCT/JP95/00838	04/27/1995
(Application Number)	(Filing Date)
(出願番号)	(出顧日)
08/578,709	12/28/1995
(Application Number)	(Filing Date)
(出願番号)	(出願日)
	·

I hereby claim benefit under 35 U.S.C. 120 of any United States application(s) or 365(c) of any PCT international application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in a listed prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge my duty to disclose any information material to the patentability of this application as defined in 37 C.F.R. 1.56 which occurred between the filing

I hereby claim domestic priority under 35 U.S.C. 119(e) of any

United States provisional application(s) listed below.

私は本宜言事内で私自身の知識に基づいてなされたすべ ての陳述が真実であり、情報および信ずるところに基づ いてなされたすべての陳述が真実であると信じられてい ることをここに宜貫し、さらに故意になされた虚偽の陳 述等々は18 U.S.C.

1001に基づき罰金あるいは拘禁または両方による処罰に あたり、またかような故意による虚偽の陳述はそれに基 づく特許出願あるいは成立特許の有効性を危うくする可 能性があることを認識した上でこれらの陳述をなしたこ とを宜言します。

date of the prior application and the national or PCT international filing date of this application:

(Status: patented, pending, abandoned) (状態:特許成立済、係属中、放棄済) (Status: patented, pending, abandoned) (状態:特許成立済、係属中、放棄済)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Japanese Language Declaration

委任状:私は下記の米国特許商標局 (USPTO) 顧客番号のもとに記載されるSUGHRUE

MION法律事務所のすべての弁護士を、同顧客番号のもと に記載される個々の弁護士はSughrue

Mion法律事務所のみの自由裁量に基づき変更され得ることを認識した上で、本特許出願の手続きおよびそれに関わる米国特許商標局との業務を遂行する弁護士として指名し、本特許出願に関するすべての通信が同USPTO顧客番号のもとに提出された住所宛に送付されることを要請します。

POWER OF ATTORNEY: I hereby appoint all attorneys of SUGHRUE MION, PLLC who are listed under the USPTO Customer Number shown below as my attorneys to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, recognizing that the specific attorneys listed under that Customer Number may be changed from time to time at the sole discretion of Sughrue Mion, PLLC, and request that all correspondence about the application be addressed to the address filed under the same USPTO Customer Number.

STATEMENT OF ACCURATE TRANSLATION IN ACCORDANCE WITH 37 C.F.R. §1.69(b):

The declaration and power of attorney is an accurate translation of the corresponding English language declaration and power of attorney.

Signature Date

04/09/7004

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

電話連絡は下記へ:

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NAME OF SOLE OR FIRST INVENTOR: 唯一あるいは第一の発明者名			: '	
Given Name (first and middle [if any]) 名 (名およびミドルネーム[該当する場合]) Tadashi	Family Name or Surname 姓		TANABE	
Inventor's signature 発明者の署名		Date 日付	Oct. 5, 2005	
Residence: 住所: Toyonaka-shi, Japan	8 · · -		Citizenship 国籍 Japan	
Mailing Address: - 郵送先: 18-13, Higashitoyonaka-cho 3-chome, Toyonaka-shi,	Osaka 560-0003 Jap	an .		
NAME OF SECOND INVENTOR: 第二の発明者名:	- !	•		
Given Name (first and middle [if any]) 名 (名およびミドルネーム[該当する場合]) Chieko	Family Name or St 姓	rname	YOKOYAMA	
Inventor's signature 発明者の署名 ににんとの しかんのであればい	. :	Date 日付	Oct. 12 2005	
Residence: 住所: Itabashi-ku, Japan			Citizenship 国籍 Japan	
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Supplemental Priority Data Sheet 優先権に関する追補データシート

Additional prior foreign applicat 追加的先行外国特許出願:	ions:		
Application Number(s) 出願番号	Country 国名	Filing Date 出顧日	Priority Claimed? 優先権の主張? Yes No 有り 無し
Additional provisional applicatio 追加的仮出願:	ns:	•	
Application Num 出願番号	ber(s)	Filing D 出 類	ate I
Application Num	ber(s)	Filing D 出願 E	<u> </u>
Application Num 出願番号 Additional U.S. or International :		<u></u> 出願日	<u> </u>
Application Num 出願番号 Additional U.S. or International s 追加的米国または国際出願: Application Number(s) 出願番号	applications: Filing 出原	出願 E	ented, pending, abandoned
Application Num 出願番号 Additional U.S. or International a 追加的米国または国際出顧: Application Number(s)	applications:	出願 E	-

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